EXHIBIT G

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO PLAINTIFF: **Carolyn Lewis (2:12-cv-04301)**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REBUTTAL REPORT OF HOWARD JORDI, PhD

Rebuttal to Thames Report

I. Summary

The reliable methods used by Jordi Labs conclusively prove that the Prolene polypropylene mesh in TVT degrades while in the human body, including the TVT mesh that was implanted in Mrs. Lewis.I was asked to analyze Mrs. Lewis' explanted TVT mesh to determine the differences, if any, between her explanted mesh compared to pristine control samples. I had no preconceived conclusions prior to starting my analysis. Thus, I analyzed the TVT mesh explanted from Mrs. Lewis initially using Scanning Electron Microscopy (SEM). After analyzing the explanted TVT mesh, it was obvious that Mrs. Lewis' mesh was different from the pristine controls. Specifically, SEM revealed obvious cracks compared to the pristine controls. However, I did not conclude from SEM alone that the cracks were degradation. Rather, I decided based on my 30 years of experience as a polymer scientist and my review of the body of scientific literature thatadditional test methods were necessary to determine if the cracks observed under SEM werea) degraded mesh; b) a biological phenomenon like biofilm; or c) a combination of physical degradation of the mesh and biofilm. Thus, a battery of tests were ordered to answer this question, including FTIR, SEM-EDX, DSC, GPC, PYMS and LCMS. Each test by Jordi Labs was supported by reliable methods for polymer analysis and was meticulously undertaken using standard operating procedures (SOPs).

The sample preparation method applied by Jordi Labs was scientifically valid. The decision to not use chemical methods for removal of proteins and other biological materials was a reliable method necessary to understand if the cracks identified by SEM were physical degradation of the mesh, tissue, biofilmor some combination of all three. The data from the testing conducted, as detailed more fully below, strongly suggest that the cracks observed under

SEM are both physical degradation of the mesh and tissue/biofilm. The FTIR microscopy confirmed that the majority of pieces that flacked off the mesh explant are polypropylene, with a small amount of tissue/biofilm.

FTIR microscopy confirmed that the cracked shards from Mrs. Lewis' explant contained polypropylene. FTIR-microscopy also showed bands at 1761 cm^{-1} and 1044 cm^{-1} and a shoulder band at ~1740 cm^{-1}indicating that polypropylene oxidized. SEM-EDX, PYMS, LCMS and DSC confirm that oxidation and environmental stress cracking are the most likely causes of the polypropylene degradation observed in Mrs. Lewis' explanted mesh. SEM-EDX analysis showed increased levels of oxygen in both the cracked and the non-cracked regions of the sample explanted from Mrs. Lewis supporting oxidation. A significant decrease in the 1st enthalpy of fusion in the DSC analysis suggested increased amorphous regions in the Lewis sample as compared to the control samples making the explant sample more vulnerable to environmental stress cracking. LCMS showed a marked decrease in the levels of DLTDP which is an antioxidant reported by Ethicon to be used for long-term stability of their mesh.

Finally, the finding that Mrs. Lewis' explanted mesh was degraded was further corroborated by analysis of 23 additional TVT and TVT-O meshes explanted from other women. Each of the methods used are detailed below and rebut the expert reports of Drs. Thames and Ong.

II. Jordi Sample Preparation Method and SEM

The sample preparation methods utilized by Jordi Labs were selected to protect the integrity and scientific reliability of the results obtained, and were necessary so that I could understand if the cracks were evidence of degraded polypropylene and/or biofilm. The methods applied represent the optimum way to prepare the samples given the totality of the tests which were to be performed, the limited sample quantity and the potential for testing artifacts following chemical treatments on the explants. It is a general principle in investigative chemistry and forensic science that the minimum amount of sample preparation required is preferred. The reason this is true is that all sample preparation no matter how carefully performed increases the risk of contamination, loss or otherwise adulterating the sample.

Samples for analysis at Jordi Labs were prepared by carefully removing portions of the tissue matrix as needed surrounding the fibers using forceps.[1] Portions of each sample were then subjected to a series of appropriate, documented sample preparation methods as specific to each technique. This is referenced in my expert report under the heading "sample preparation" with each technique. The technique specific sample preparation procedures were based on good scientific principles using established Jordi Labs standard operating procedures (SOP) and have been validated by over 30 years of experience in analytical polymer chemistry, and the body of scientific literature. Pertinent method information was further documented in laboratory notebooks and the SOP utilized was cited in the analysis conditions section of my expert report.

[1] Expert Report of Dr. Howard Jordi, Pg 15

Literature references for each method utilized were further provided in the background section of my expert report.

Dr. Ong alleges that the SEM results provided in my expert report are not valid as the samples were not subjected to "reagents to remove such tissue and biological material."Dr. Thames makes a similar statement about removal of tissue as relates to FTIR testing.[2] Dr. Ong also states that "the SEM images from Dr. Jordi's expert report show the presence of gross tissue, possible organic material and cells on the mesh."[3] He then claims that the results reported are invalid because they cannot be attributed to only oxidation indicating they may be due to biofilm. Thus Dr. Ong first states that he can distinguish the difference between gross tissue, possible organic material and cells on the mesh and then he claims that I cannot distinguish them. One skilled in the art can identify the difference between the various materials based on their morphologies. Please see Figure 1 for an example of the difference between tissue, and the cracked polypropylene surface. The presence of residual tissue was not unexpected or unknown to us as it was in fact stated in my expert reporton page 15 and again on page 18.[4,5] This was anticipated and was considered when developing the testing plan.

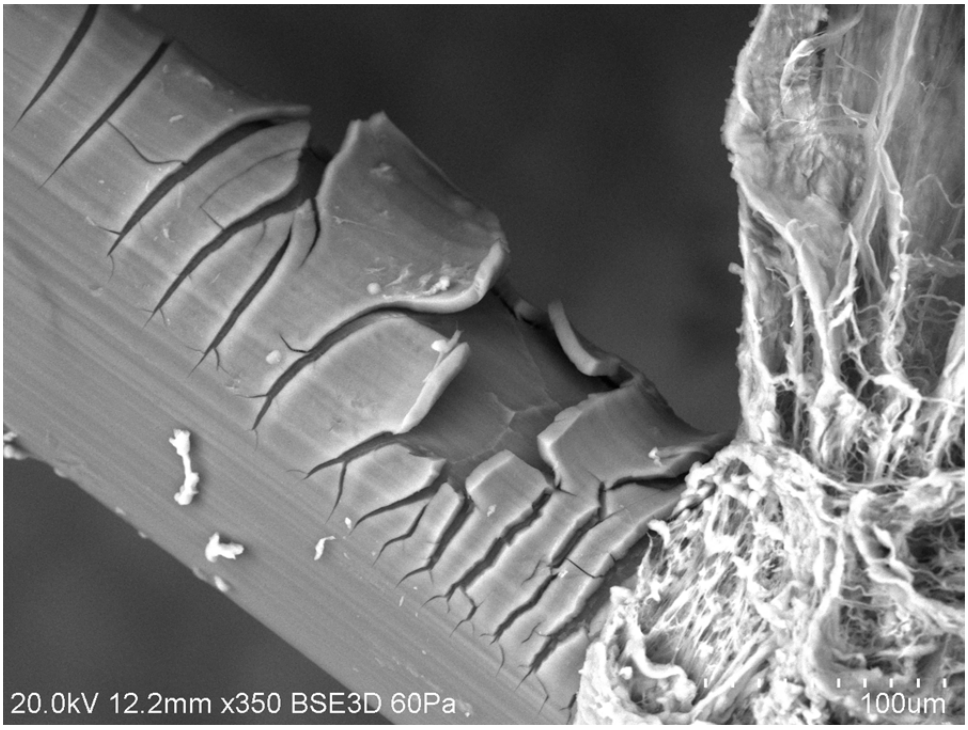

Figure 1. Jordi SEM for Sample J7959 13409

[2]Expert report of Shelby F. Thames. Ph.D., P.E, Pg. 7
[3]Expert report of Kevin L. Ong. Ph.D., P.E, Pg. 20
[4] Expert Report of Dr. Howard Jordi, Pg 15
[5] Expert Report of Dr. Howard Jordi, Pg 18

The real issue is not the presence of tissue matrix but rather the contention by Dr. Ong and Dr. Thames that the cracked material present on the fibers is what they termed biofilm. This contention was made based on a single literature reference.[6]The de Tayracreference discusses removal of a cracked material from the surface of polypropylene fiber explants but contains no written procedure as to how the cracked material was removed beyond stating that DMSO with ultrasonic shock was applied. The duration, temperature, sonication intensity and other pertinent parameters are not provided. Furthermore, this literature reference did not characterize the product which was removed using any chemical analysis methods for the characterization of either polypropylene, biofilm or tissue. Thus the statement that the material removed from the fiber surface was solely biofilm has no scientific basis since no chemical characterization was performed. Thus, the opinion that the material removed was only biofilm is entirely baseless without chemical analysis and that the opposite conclusion is supported by Dr. Ong'sown SEM study as the "alleged" biological film did not dissolve even following extensive use of reagents intended to remove tissue.

Importantly, Dr. Ong and Dr. Thames also did not use any chemical characterization methods to analyze the material removed from the fiber surface and thus have no basis for their statement that the material is solely biofilm. Removing a material from a surface does not prove its chemical identity. They further reported no efforts to collect and analyze the cracked surface material. This is curious considering the fact that FTIR microscopy was utilized to characterize the intact fibers and thus this technique was known to Dr. Ong and Dr. Thames and could have been readily applied as it was in my work.

In my work, the fiber mesh samples were not treated with chemical reagents to remove the tissue. This was done intentionally as explained above and is not unprecedented in the literature as other authors also did not subject the samples to chemical pretreatment prior to SEM analysis.[7] More importantly removal of all biological material is not required because the cracked material was being collected from the fiber surface and characterized by FTIR microscopy. Thus an independent method was being used to confirm the identity of the cracked surface material. This method is scientifically preferred as compared to only examining SEM images as FTIR is one of the most well established and recognized methods for chemical identification as cited in our expert report on page 66 and as confirmed by Dr. Thames in his expert report.[8] Chemical analysis by FTIR microscopy can readily distinguish the difference between polypropylene and biological material such as tissue/biofilm. This was conceded by Dr. Thames in his expert report when he stated that "The Carolyn Lewis FTIR spectra did confirm the presence of proteins."[9] FTIR could not confirm the presence of proteins unless it could also distinguish the two materials. Please see our discussion of FTIR below for additional information on confirmation of polypropylene by FTIR.

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[6]Renaud de Tayrac and Vincent Letouzey, *International UrogynocologicalJorunal*22 (2011) 775-780.
[7]Arnaud Clave, Hanna Yahi, Jean-Claude Hammou, SuzeleiMontanari, Pierre Gounon and Henri Clave, International Urogynecology Journal and Pelvic Floor Dysfunction 21 (2010) 261-270.
[8]Expert report of Shelby F. Thames. Ph.D., Pg. 7
[9]Expert report of Shelby F. Thames. Ph.D., Pg. 9

The argument that the use of reagents to remove tissue would not have prevented analysis by FTIR neglects several important issues. First, the methods reported in the literature for removal of tissue generally rely on the use of oxidizing agents. This includes Dr. Ong'smethod which used NaOCl and nitric acid which are both known to be strong oxidizers.[10,11,12] Since one of the questions under study was the oxidation of the polypropylene mesh, it is my position that the use of oxidizing agents as a part of the sample preparation process should be avoided. Especially since the removal of tissue is not a necessary prerequisite in order to use FTIR to look for indications of oxidation. Nor is it required in SEM-EDX if one is able to distinguish the difference between tissue and polypropylene as we contend and as Dr. Ong inadvertently admitted when he stated that the SEM images in my report show the presence of "gross tissue, possible organic material, and cells on the mesh."[13] Lastly, previous testimony by Dr. Burkley of Ethicon alleged that the use of reagents to remove tissue and the associated drying steps could cause cracking. If this were in fact the case, then this method would be inappropriate.[14]

DSC analysis on the fibers would only be adversely affected if a significant weight fraction of the sample was not polypropylene. Care was taken to ensure no gross tissue was present with the fibers during sampling for DSC. Since I used FTIR to confirm the chemistry of the surface layer as primarily polypropylene, it is my position that the decision to analyze the fibers directly was appropriate.

It is further my position that the remaining methods utilized in forming my opinions, including GPC, QTOF-LCMS and PYMS would not be adversely affected by the presence of protein or other biomaterials. In the case of GPC, biomaterials would not dissolve in the solvent used to prepare the sample for GPC and thus would have been excluded. QTOF-LCMS and PYMS are both mass spectroscopy methods and have the ability to distinguish between components of different chemistry. Mass spectroscopy is well known to be "the most widely applicable of all the analytical tools... capable of providing information about... the qualitative and quantitative composition of complex mixtures."[15] These methods are appropriate for analysis of complex mixtures and were being applied to examine the samples for antioxidants which could be readily distinguished from the sample matrix. Thus the presence of residual biological material if present is irrelevant. The supposition of encapsulation of the fibers by biofilm which could prevent extraction for LCMS has no scientific basis as Dr. Thames did not cite any literature references supporting this contention nor provide any evidence to justify it.[16]

The removal of the tissue matrix is a simple process which involved no more than using forceps to grasp the tissue matrix and then using a second set of forceps to pull away pieces of

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[10]Lewis, R., "Condensed Chemical Dictionary," Thirteenth edition, Van Nostrand Reinhold Publishing, New York, Pg. 791 and1019, 1997.
[11]O,Neil, M., Heckelman, P., Koch, C., Roman, K., Kenny, C., Arecca, M., "The Merck Index," Fourteenth Edition, Merck & Co., Inc., Pg 1138, 2006.
[12] Brady, J., Humiston, G., "General Chemistry, Principles and Structure," John Wiley and Sons, 1986, pg. 723
[13]Expert report of Kevin L. Ong. Ph.D., P.E, Pg. 20
[14] Deposition of Daniel f. Burkley, M.S., Pg 136
[15]Skoog, D., Holler, F., Niemann, T., "Principles of instrumental Analysis," Saunders College Publishers, 1998, pg. 498.
[16]Expert report of Shelby F. Thames. Ph.D., Pg. 17

the matrix until the fibers were revealed.[17] This process was performed by Dr. AdiKulkarni.[18]The use of forceps does not require a special procedure and is a basic laboratory skill possessed by Dr. Kulkarni. Standard operating procedures are not typically written for rudimentary tasks of this nature as the skills required are present due to experience.

Ethicon's experts argue that no rationale was offered by me for the cracks being perpendicular to the draw direction.[19] It was an important observation in our SEM findings which mirrored the SEM findings by a number of other studies including Dr. Thames' own study and the 7 year dog study by Ethicon. **Figure 1** clearly demonstrates that the cracks propagate in a direction perpendicular to the direction of the draw. An explanation for this phenomenon can be found in a literature report by Celine et al where the authors of that publication state that "The reason for this phenomenon in oriented polypropylene monofilaments has been explained by their pronounced skin/core structure. This bicomponent structure is created by the differential cooling rates between external and internal layers of the monofilaments during the melt spinning process, which leads to the formation of a low order nonfibrillar outer skin a few microns thick, and a highly oriented crystalline fibrillar inner core."[20] They further mention that "…the outer skin is more susceptible to oxidative degradation than the fibrillar inner core. Cleavage of the polymer chains causes relaxation of the folded lamellae, increases in crystallinity and density, and contraction localized to the outer skin. This in turn leads to regular circumferential crack formation at the surface, but only to the depth of the outer layer." This is a plausible explanation of the observed phenomena.In another literature report, Blais et al described a possible reason for circumferential cracking as follows: "The formation of cracks in the outer PPH sheath (Fig. 3) during this oxidation process can be rationalized in terms of chemicrystallization which results from the cleavage of tie molecules in the disordered region between lamellae or at microfibril ends by the β-scission (Reaction 1). The cleaved chains in the surface zone can then relax into the fold structure, with a corresponding increase in density, and so lead to surface contraction and cracking."[21]Furthermore, even though the fibers used in this study were not implanted in a human body, they showed circumferential cracks similar to the ones observed in my report, Dr. Thames report as well as Ethicon's 7 year dog study.

In summary, it is my opinion that the sample preparation procedures were well selected based on well established scientific procedures as evidenced by SOPs developed over more than 30 years of analytical experience. It is further our contention that the decision to not use "reagents to remove such tissue" was well founded and based on the fact that independent verification of the chemistry of the cracked surface material was being performed using FTIR microscopy, and allowed me to analyze andreliably answer the question whether the cracked pieces observed under SEM was degradation and/or biofilm. The decision to not use reagents to

[17] Deposition of Howard C. Jordi, Ph. D., Pg 49-52
[18] Deposition of Howard C. Jordi, Ph. D., Pg 49-52
[19] Expert Report of Shelby F. Thames, Ph.D.; Pg7
[20]Celine Mary, Yves Marois, Martin W. King, GaetanLaroche, YvanDouville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, *ASAIO Journal*, 44 (1998) 199-206.
[21]P. Blais, D. J. Carlsson, F. R. S. Clark, P. Z. Sturgeon and D. M. Wiles, Textile Research Journal 46 (1976) 641

remove tissue is not without precedent in the literature and does not invalidate our SEM results.[22] It most certainly does not invalidate our FTIR results as the intended purpose of this method was distinguishing between different chemistries.

Lastly, Dr. Ong and Dr. Thames contention that the sample preparation methods are inappropriate due to the presence of biofilm is entirely unfounded as they presented no evidence of a biofilm layer and cited only a single reference article which also presented no chemical identification of the surface layer. We note that Dr. Ong and Dr. Thames could have easily provided this evidence by performing FTIR microscopy analysis confirmed on the cracked surface material in the same way that we did but neglected to do this even though they used this technique for other purposes.

III. Exponent Sample Preparation Method and SEM

In Dr. Ong's expert report he describes the procedure which they utilized for "tissue digestion and cleaning in order to facilitate analysis of the mesh materials."[23]He provides a table on page 19 showing a lengthy **20-STEP PROCESS** used to clean the samples!

The literature references cited by Dr. Ongin support their claim of the reliability of this 20-step process used a number of different methods to remove tissue. The first was treatment with DMSO followed by sonication.[24] The second method was treatment with NaOCl for 2hrs at 37ºC.[25]The third reference did not provide a method for digestion of tissue but rather detailed that a macroscopic sample was cleaned with soap and deionized water and that NaOCl was used to sterilize the sample with no discussion of tissue removal.[26] The fourth reference cited digestion of tissue using three methods but was not for polypropylene but for ultrahigh molecular weight polyethylene wear debris. The three methods used on the polyethylene included treatment with nitric acid, strong bases and enzymatic digestion using Proteinase K among others.[27]The last reference provided a wide range of methods but the only one which was relevant to the methodology used by Dr. Ong was nitric acid digestion. It is noted that polypropylene was not mentioned in this article and that this method does not provide specific guidance related to polypropylene.[28]

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[22]Arnaud Clave, Hanna Yahi, Jean-Claude Hammou, SuzeleiMontanari, Pierre Gounon and Henri Clave, International Urogynecology Journal and Pelvic Floor Dysfunction 21 (2010) 261-270.
[23]Expert report of Kevin L. Ong. Ph.D., P.E, Pg. 17
[24]Renaud de Tayrac and Vincent Letouzey, *International UrogynocologicalJorunal*22 (2011) 775-780.
[25]Guidoin, M. F., Y. Marois, J. Bejui, N. Poddevin, M. W. King and R. Guidoin Biomaterials 21 (23) (2000) 2461-2474.
[26]Choma, T. J., J. Miranda, R. Siskey, R., Baxter, M. J. Steinbeck and S. M. Kurtz. J. Spinal Discord Tech. 22(4) (2009) 290-296.
[27] Baxter, R. M., M.J. Steinbeck, J. L. Tipper, J. Parvizi, M. Marcolongo and S.M. Kurtz, J. Biomed Mater Res B Appl Polymer, 91 (1) (2009) 409-418.
[28]American Society for Testing and Mterials (2005). ASTM F561-05a: Standard practice for retrieval and analysis of mediccal devices, and associated tissues and fluids. West Conshocken, PA, ASTM international.

It is noted that of the five references cited in relation to the sample preparation process only one is for a polypropylene fiber and this methodology was not applied.[29]In no case did we find an example in the literature of multiple treatments used on the same sample. In comparison, Dr. Ong's process included NaOCl digestion which was done four times in steps 3, 4, 17 and 18. This was followed bya very aggressive 70% Nitric acid digestion which was done three times in steps 7, 8 and 10 and enzymatic digestion which was done twice in steps 13 and 14. Thus a total of 9 cleaning processes were performed on the samples. In my opinion this method is very excessive and exposes the samples to potential damage. There is no literature precedent provided for such a method.

The procedure applied by Dr. Ong used NaOCl digestion four times in steps 3, 4, 17 and 18. In comparison, the six literature references we reviewed which used NaOCl never used more than a single treatment and in 5 of the 6 references this was done for only 2hrs at 37ºC.[30, 31, 32,33, 34] In comparison, Dr. Ong treated the samples for up to 15hrs as a part of just one of the four treatments. Dr. Ongsupplies no explanation or justification for this extended process. Nor does he provide any rational or evidence that this would not harm the sample.

Dr. Ong then applied an even more aggressive 70% Nitric acid digestion three times in steps 7, 8 and 10. Nitric acid which is 70% pure is known as concentrated nitric acid and is a strong oxidizing agent. This acid is known to react violently with "combustible or readily oxidizable materials including alcohols."[35,36,37]It was noted that nitric acid was reported to be very efficient for formalin fixed tissue removal resulting in less than 1% residual tissue.[38] The samples analyzed in this study were formalin treated. In the ASTM method cited by Dr. Ong it stated that "concentrated nitric acid (HNO_3) has been used when tissues are difficult to digest, especially after fixation and embedding."[39] While this would be expected to ensure no tissue remained, it might also result in sample oxidation. Nitric acid is reported to be a stress cracking agent for polypropylene in the literature. Dr. Thames should be aware of this as he cited a paper

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[29]Renaud de Tayrac and Vincent Letouzey, *International UrogynocologicalJorunal*22 (2011) 775-780.
[30]C.R. Costello, S.L. Bachman, S.A. Grant, D.S. Cleveland, T.S. Loy and B.J. Ramshaw, Surgical Innovation 14 (2007) 168-176.
[31]C. R. Costello, S. L. Bachman, B. J. Ramshaw and S. A. Grant, Journal of Biomedical Materials Research Part B: Applied Biomaterials 83B (2007) 44-49.
[32]Matthew J. Cozad, David A. Grant, Sharon L. Bachman, Daniel N. Grant, Bruce J. Ramshaw, Sheila A. Grant, J Biomed Mater Res B ApplBiomater, 94 (2010) 455-462.
[33]Arnaud Clave, Hanna Yahi, Jean-Claude Hammou, SuzeleiMontanari, Pierre Gounon and Henri Clave, International Urogynecology Journal and Pelvic Floor Dysfunction 21 (2010) 261-270.
[34]Gina Sternschuss, Donald R. Ostergard, Hiren Patel, The Journal of Urology, 188 (2012) 27-32.
[35]Lewis, R., "Condensed Chemical Dictionary," Thirteenth edition, Van Nostrand Reinhold Publishing, New York, Pg. 791, 1997.
[36]O,Neil, M., Heckelman, P., Koch, C., Roman, K., Kenny, C., Arecca, M., "The Merck Index," Fourteenth Edition, Merck & Co., Inc., Pg 1138, 2006.
[37] Brady, J., Humiston, G., "General Chemistry, Principles and Structure, John Wiley and Songs, 1986, pg. 723
[38] Baxter, R. M., M.J. Steinbeck, J. L. Tipper, J. Parvizi, M. Marcolongo and S.M. Kurtz, J. Biomed Mater Res B Appl Polymer, 91 (1) (2009) 409-418.
[39]American Society for Testing and Materials (2005). ASTM F561-05a: Standard practice for retrieval and analysis of mediccal devices, and associated tissues and fluids. West Conshocken, PA, ASTM international.

which indicates this in his expert report as reference 27.[40]It is my opinion that nitric acid is not a scientifically valid choice for sample preparation given that in this study I was examining the extent of cracking in the fiber mesh. The references listed by Dr. Ong in relation to nitric acid are for cleanup of polyethylene and not polypropylene samples and therefore do not provide justification for the use of this method.

After completing multiple NaOCl treatments, and two nitric acid treatments, Dr. Ongwent even further and used an enzymatic digestion using proteinase K. Lastly, Dr. Ong repeated the NaOCl treatments previously performed. The length and severity of this sample preparation process are inexplicable given the literature and are in our opinion highly excessive. No SOP or similar documentation was cited indicating that this method had been validated by previous experience nor predetermined.

SEM images of the explant fiber mesh for Carolyn Lewis were reported to be taken following each cleaning cycle. Figure 2 shows the fibers following the last two cleaning cycles as reproduced from Dr. Ong's report. The presence of the cracked surface layer is readily visible in all SEM images even following this extensive cleaning process. This directly contradicts Dr. Ong's statement that the material on the surface is solely biofilm and not cracked polypropylene. Instead of recognizing this fact, Dr. Ong proceeds to cite the small amount of loss in the cracked material as proof of biofilm. Dr. Ong neglects to point out that the sample treatment applied included both orbital shaking and sonication (ultrasonic shock). The later of these two methods supplies mechanical shearing force which readily explains the limited flaking off observed in the cracked surface material.[41] The samples were subjected to ultrasonic shock during each cycle for a total of four times. As stated in my expert reportand during mydeposition, Iobserved that the surface layer was brittle and loosely attached such that when fibers were rolled on an FTIR substrate pieces of the cracked surface material came off.[42] In my expert report, I analyzed this material by FTIR-microscopy which clearly identifies all the polypropylene FTIR bands along with proteins.

The SEM data presented in Dr. Ong’s report does not allow for a direct comparison of the fibers before and after the sample cleaning process. The magnification presented in figure 9 of Dr. Ong’s report shows the material before cleaning at a magnification of 26x while that after cleaning was presented at 100x and 250x for the first cleaning cycle and 250x and 500x for the second and third cleaning cycles. This discrepancy along with an inability to identify which fiber is being examined in the later images as compared to the initial image makes a direct comparison impossible. Since significant variation in the extent of cracking is seen region to region, only a comparison between cycles 3 and 4 of the cleaning process is scientifically valid.

Dr. Thames observations that the peeling layer is not integrated into the smooth PP fiber who's extrusion lines are running perpendicular to the exterior surface layer is in keeping with

[40]Chatten, R. and Vesely, D., "Environmental Stress Cracking of Polypropylene." Polypropylene- An A-Z reference, Ed. J. Karger-Kocsis. London: 1999, 212.
[41] Deposition of Howard C. Jordi, Ph. D., Pg 61-62.
[42] Deposition of Howard C. Jordi, Ph. D., Pg.*61. line 4-10*

other published reports for degraded PP fibers.[43] In somereports, degradation was intentionally created.[44] This contradicts his contention that the cracking must occur in the fiber draw direction.

Dr. Thames presents measurement of the thickness of the fibers and states that there is no significant difference between the Exemplar and Lewis explant samples.[45] This analysis neglects to note that the cracked surface material was 3um thick.[46]Therefore the relevant thickness difference falls within the experimental error which was reported in Table 2 on page 25 to be 7-7.8um. If the 3um thick cracked layer had been removed from the surface using the 20-step process, the diameter would be reduced by 3-6um and thus it would not show a statistically significant change in the diameter as measured by SEM.

Dr. Thames then describes the outer layer on the Lewis sample as formaldehyde fixed protein.[47] This is in spite of the fact that the samples in question were subjected to the process which was intended to remove all biological material. This is a logical inconsistency. If the 20-step process utilized removed all biological material, it is not clear why is it still observed in the images provided. In addition, this process goes beyond what is typically done. Also, Dr. Thames presents no characterization data for the identification of the surface layer. Therefore, this statement is both logically inconsistent and not supported by established data.

It is also striking that there is no indication in the report that Ethicon's experts attempted to identify the chemistry of the cracked material released from the surface using FTIR Microscopy. This method was utilized in their report and could very readily have been applied to examine the chemistry of the cracked material released from the surface.

In the light of the obvious contradiction between Dr. Ong's contention that the cracked surface is solely biofilm and the SEM images he produced which show that the cracked surface layer persists even after the extensive cleaning procedures, it is my opinion to a reasonable degree of scientific certainty that the data in Dr. Ong's report provides further support for my opinion that the surface layer is not biological in nature and is further evidence that polypropylene in TVT degrades and in fact did degrade in Mrs. Lewis' body before being explanted.

In the light of the conspicuous absence of characterization data and this obvious contradiction, I believe that the idea that the cracked material was solely biofilm is scientifically unsound and baseless. Indeed, the picture on the bottom in Figure 2 below,is evidence that the process utilized by Dr. Ong simply sheared off the cracked and degraded outer layer of the polypropylene leaving obvious abrasions on the explanted sample, but did not remove all of the

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[43]Celine Mary, Yves Marois, Martin W. King, GaetanLaroche, YvanDouville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, *ASAIO Journal*, 44 (1998) 199-206.

[44]P. Blais, D. J. Carlsson, F. R. S. Clark, P. Z. Sturgeon and D. M. Wiles, "The Photo-Oxidation of Polypropylene Monofilaments3: Part II: Physical Changes and Microstructure" Textile Research Journal 46 (1976) 641

[45] Expert Report of Shelby F. Thames, Ph.D.; page 25, Table 2

[46] Expert Report of Shelby F. Thames, Ph.D.; Pg 26, Figure 11

[47] Expert Report of Shelby F. Thames, Ph.D.; Pg26

cracked and degraded surface area of the mesh. This is what one would expect after a 20-step process using oxidizing reagents and ultrasonic shock on an already degraded polypropylene explant.

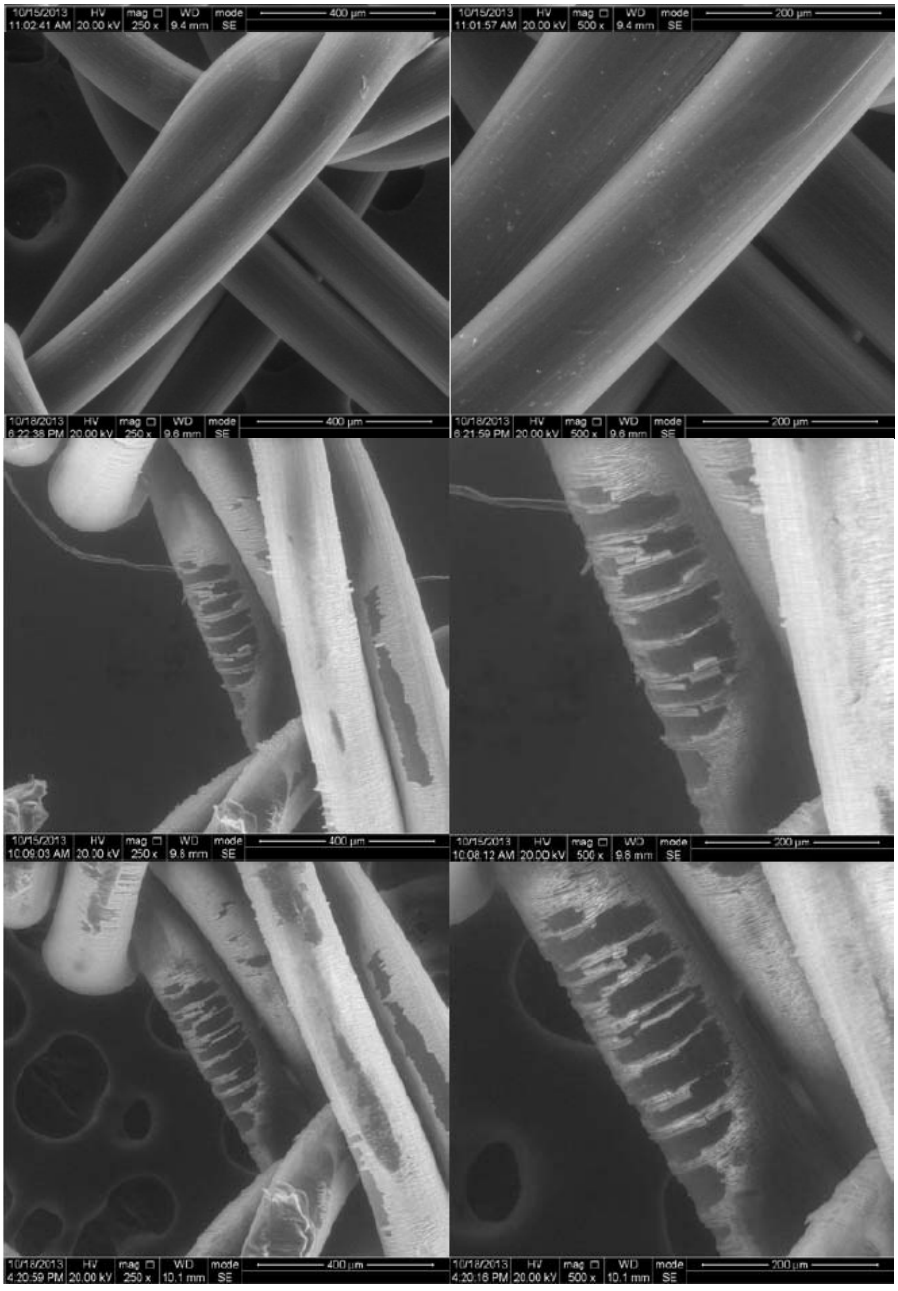

Figure 2: Reproduction of portions of Figures 9 and 10 from the Expert report of Kevin L. Ong. Ph.D., P.E. showing the exemplar mesh samples after the 4th reagent processing cycle (top), the Lewis Explant Sample #1 after 3rd reagent processing cycle (middle) and the 4th reagent processing cycle (bottom).

IV. Polypropylene degradation and stability

Dr. Thames opines that "Although it is very difficult to create a polymer, or anything else for that matter, unreactive in all environments, the choice of a hydrocarbon polymer like PP is as good as one can get for this application."[48] This is contrary to the peer-reviewed literature. A study by Celineet al reported in 1998, clearly mentions that "After 1 and 2 years in vivo, the explanted polypropylene sutures showed visual evidence of surface stress cracking. This was not found in the explanted polyvinylidene fluoride sutures.[49] These results suggest that polyvinylidene fluoride may be more biostable than polypropylene in the long term."Additionally, one of the conclusions of Ethicon's 7 year dog study states that "Degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking."[50] Thus it appears that polypropylene is not as good as one can get for this application.

Dr. Thames suggests that exposure to light and water in combination with temperature are potentially the most likely to initiate molecular weight changes in polypropylene.[51] However, polypropylene degrades in any environment enriched in free radicals. The radical degradation of polypropylene is a well-known phenomenon.[52,53] The mechanism is also outlined in my expert report. The generation of free radicals by macrophages (blood cells) is no longer in question.[54]Macrophages in the body produce large amounts of both superoxide (O_2^-) and hydrogen peroxide (H_2O_2) when faced with infectious agents or other foreign materials. These are very powerful oxidants and one cannot ignore their attack on polypropylene as one of the most important factors contributing to the oxidation *in vivo*.

In my expert report, it is stated that "The physiological environment in the human body does not involve many of these conditions such as exposure to light. For a non-hydrolyzable hydrophobic polymer such as polypropylene, oxidation and biodegradation pathways are the most pertinent."[55] Hydrolysis as a cause for degradation in polypropylene has been ruled out. However, Dr. Thames dedicated an entire section in his report to this mechanism. Based on Dr. Thames' argument it is clear that he believes that if a polymer is water stable, it can be implanted in the human body without "any meaningful or harmful degradation."[56] This once again points to

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[48] Expert Report of Shelby F. Thames, Ph.D.; Pg 2

[49]Celine Mary, Yves Marois, Martin W. King, GaetanLaroche, YvanDouville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, *ASAIO Journal*, 44 (1998) 199-206.

[50] ETH.MESH.09557798, 7 Year Dog Study with explant images

[51] Expert Report of Shelby F. Thames, Ph.D.; Pg3

[52]Cornelia Vasile, Degradation and decomposition, in *Handbook of Polyolefin*, eds.CorneliaVasile and Raymond B. Seymour (Marcel Dekker Inc, New York, USA) 1993, 479-552.

[53] A. Ravve, Degradation of Polymers, in *Principles of Polymer Chemistry 2nd Ed.*, (Kluwer Academic/Plenum Publishers, New York, USA) 2000. 581-616.

[54] S. A. M. Ali, S. -P. Zhong, P. J. Doherty and D. F. WIlliams, *Biomaterials* 14 (1993) 648-656.

[55] Expert Report of Howard Jordi, Ph.D ; Pg.5

[56] Expert Report of Shelby F. Thames, Ph.D.; Pg. 4

Dr. Thames' lack of understanding of the free radical attack mechanism as being the major cause of polypropylene degradation.

Under the heading oxidative degradation, Dr. Thames implies that polypropylene cannot oxidize under conditions below 150 °C.[57]This is patently false as it ignores the role of the radical formation mechanism in degradation. If a low temperature source of radicals is present then high temperature is not needed. Liebert et alconducted a study in 1976 where they compared the polypropylene explants with and without antioxidants explanted from hamsters.[58]The conclusion of that study was that the polypropylene explants without antioxidants showed signs of severe degradation where as the polypropylene explants with antioxidants showed no signs of degradation. This proves that oxidation was possible in the biological environment. Dr. Thames in his expert report did not contest the finding listed in this literature reference.[59]Dr Thames assumes that the mechanism of degradation is thermal degradation. When in fact I opined that reactive oxygen species produced by macrophages to be the major cause, an opinion supported by the medical and scientific community. Radical formation does not require elevated temperature depending upon the source of the radicals. This is a logical fallacy and a misunderstanding of the mechanism I am proposing for the surface oxidation.

My expert report did note hydrolysis as a factor for polymer degradation in general. A list of several other mechanisms isalso listed inmy expert report.[60] In addition, it is also noted that "The physiological environment in the human body does not involve many of these conditions such as exposure to light. For a **non-hydrolyzable** hydrophobic polymer such as polypropylene, oxidation and biodegradation pathways are the most pertinent and will be discussed in detail below."

An inference ofDr. Thames' understanding of the 7 year dog study by Ethicon is that he believes that the septic environment in a human pelvis is the same as an aseptic environment in a dog's heart and that the results from the dog study are directly applicable by inference to the human pelvis.[61]This is in spite of the fact that inflammation levels will be greater in a contaminated human pelvis. This implies the presence of many inflammatory cells such as macrophages which will produce copious amounts of hydrogen peroxide and superoxide. These species will attack the polypropylene surface. In fact, Williams in his 1991 article states "The generation of hydrogen peroxide in biological systems, especially from phagocytic cells is no longer in question, and very little could be argued on the autooxidation of some polymers by free radicals."[62]

Dr. Thames states that my report is misleading in respect to the literatures statements regarding the oxidation of polypropylene as I cited references which discussed

[57] Expert Report of Shelby F. Thames, Ph.D.; Pg 12
[58] Timothy C Liebert, Richard P. Chartoff, Stanley L. Cosgrove and Roberts S. McCuskey*Journal of Biomedical Materials Research* 10 (1976) 939-951.
[59] Expert Report of Shelby F. Thames, Ph.D.; Pg 15
[60] Expert Report of Howard Jordi, Ph.D ; Pg 5
[61]Expert Report of Shelby F. Thames, Ph.D.; Pg 4-5
[62]David F. Williams and Sheng P. Zhong, Adv. Matter, 3 (1991) 623-626.

unstabilizedpolypropylene.[63] Dr. Thames's interpretation of my opinions is incorrect. I am well aware of the Liebert study and its conclusions. The all-important conclusion from the Liebert study is that polypropylene degrades in a biological system when not stabilized by an antioxidant. Dr. Thames insinuates that I knowingly tried to mislead the reader since I was aware of the presence of the antioxidants in the Prolene meshes. However, since Dr. Thames reviewed my report he should also know that I presented evidence that showed the loss of antioxidant from the explanted fibers. In fact, I examined the relative concentration of two antioxidants viz. Santonox R and Dilauralthiodiporopionate (DLTDP) in Ethicon's pristine and explant samples and found a significant reduction of additive levels in the explants. According to Ethicon,Santonox R (0.10-0.30%)is used as an antioxidant to promote stability during compounding and extrusion and DLTDP (0.40-0.60%)is used as an antioxidant to improve long-term storage of the resin and the fiber and to reduce the potential oxidative reaction with ultraviolet light.[64]It appears that according to Ethicon's own documents, DLTDP which is at least twice as abundant and promotes long term stability to polypropylene is the more important of the two. In Table 18 of the my expert report, it is clearly noted that the DLTDPrelative concentration is orders of magnitude lower in the explants as compared to the untreated or the formalin treated controls. Thus, Dr. Thames statement is misleading as he was aware that the DLTDP results also pointed to loss of antioxidants.

V. FTIR and FTIR-Microscopy

The purpose of myFTIR analysis was two-fold. The main goal was to identify the cracked material on the fiber surface. Secondarily, it was desired to determine if the material on the surface was oxidized. This question has no meaning unless the cracked material was found to be polypropylene. My identification of the surface material as polypropylene was not even disputed in Dr. Thames' report even though this is of profound importance. A total of 5 samples and 10 discreet particles were analyzed and all confirmed that the cracked material contained polypropylene. The FTIR reference standard used in the analysis was from the Sadtler library.[65] Dr Thames seems to have overlooked the fact that the cracked material which was analyzed showed strong evidence that it contained polypropylene.

Dr. Thames stated that it is "telling" that only 5 of 23 samples were analyzed by FTIR Microscopy.[66] This is a curious statement when one considers that Dr. Thames analyzed only a single explant sample and a single control even though they had access to all the same samples as I did. The sample size prevented analysis by all methods for all samples. Nevertheless, it remains my scientific opinion that 5 samples and 10 particles is more than necessary for significance in this testing, and reliably confirmed that the polypropylene in TVT degrades and that the TVT implanted in Mrs. Lewis degraded while in her body.[67]

[63] Expert Report of Shelby F. Thames, Ph.D.; Pg15
[64] ETH.MESH.02268619 – Prolene Resin Manufacturing Specifications
[65] Diamond Shamrock Corporation, Sadtler Library
[66] Expert Report of Shelby F. Thames, Ph.D.; Pa7
[67]Hibbert, D., Gooding, J., Data Analysis for Chemistry' An introductory guide for students and laboratory scientist, Oxford University Press (2006) Pg. 37.

Figures 3, 4 and 5 below show the FTIR spectrum of particles collected from the Mrs. Lewis explant sample overlaid with polypropylene control sample and human albumin respectively.

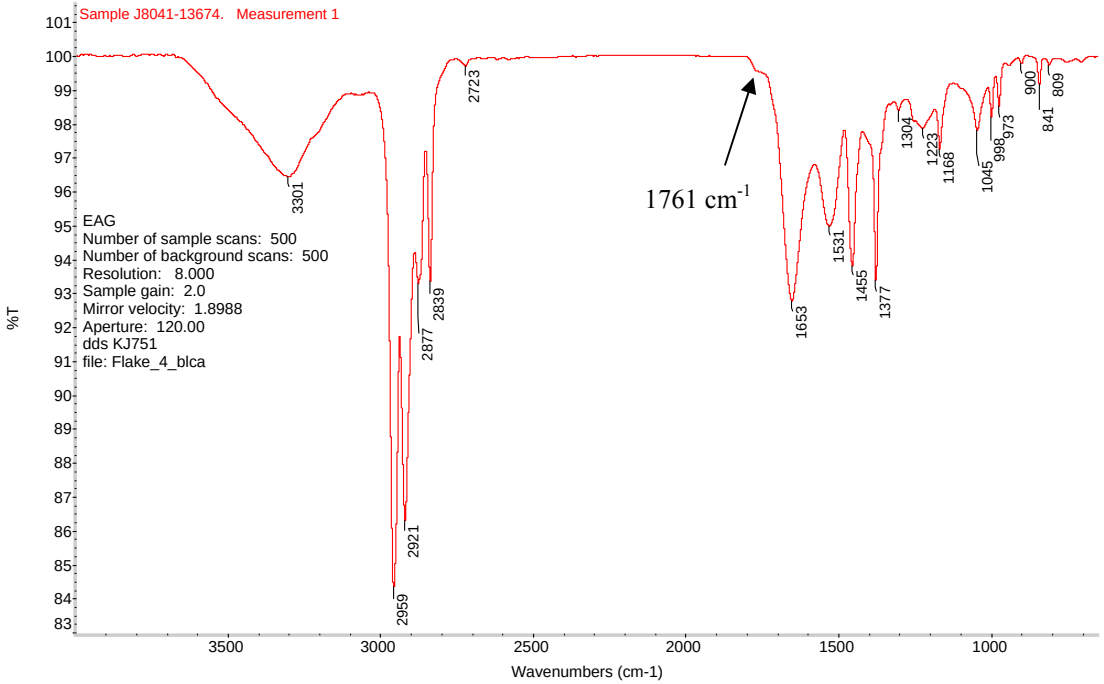

Figure 3. FTIR spectrum for particle collected from Mrs. Lewis explant sample

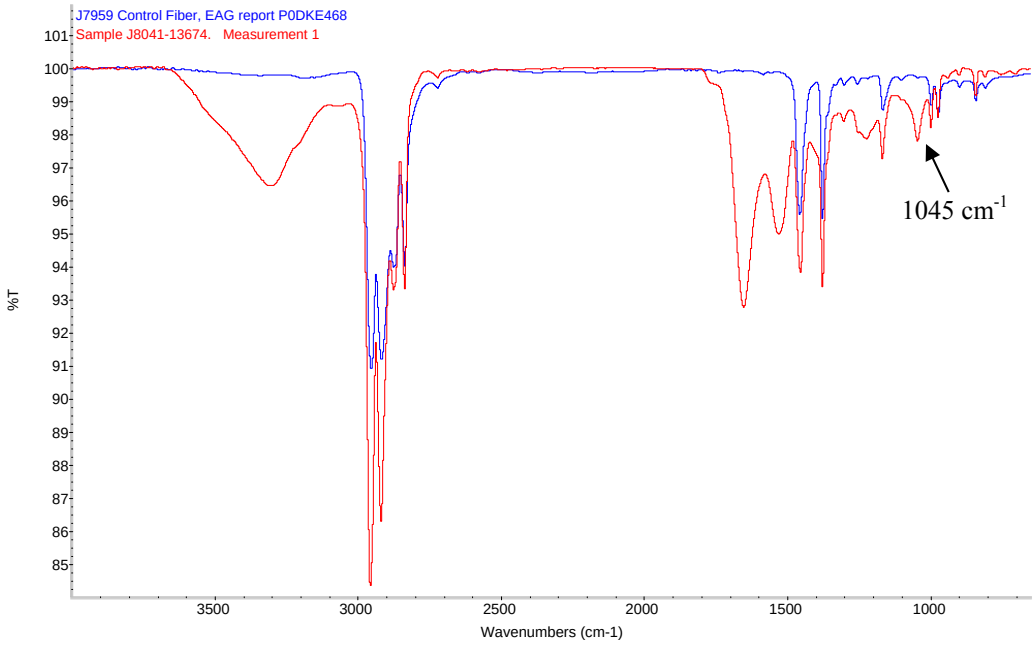

Figure 4. Overlay of the FTIR spectra of particles collected from Mrs. Lewis sample and Control fiber

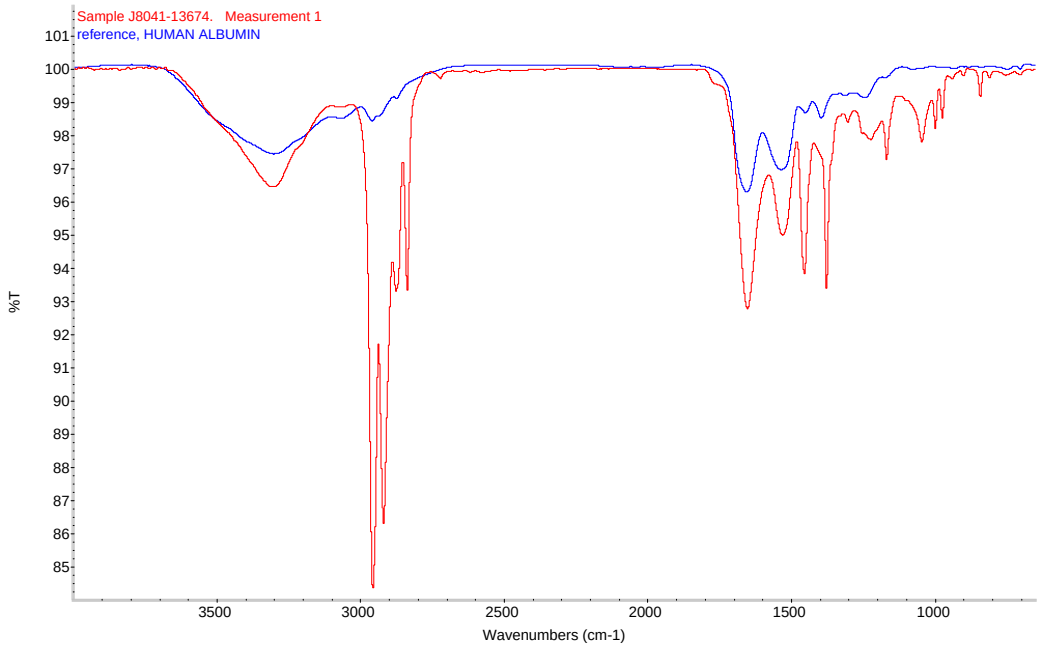

Figure 5. Overlay of the FTIR spectra of particles collected from Mrs. Lewis sample and Human Albumin

The most important observations from these spectra are the following:

1. The FTIR spectrum of particles collected from Mrs. Lewis sample confirmed the presence of polypropylene as the bands in the fingerprint region viz. 1457, 1377, 1166, 998, 974 and 840 cm^{-1} were all present.[68,69]
2. The FTIR spectrum also showed the presence of protein in addition to polypropylene as shown in Fig. 5
3. As indicated in Figs. 3 and 4, two distinct bands and one shoulder were observed in the explant sample at 1761,~1740 and 1044 cm^{-1}that were not observed in the control. The bands at 1761 and 1740 $cm^{-1}$are indicative of carbonyl groups and 1044 $cm^{-1}$is indicative of a C-O-C group all of which indicate oxidation.[70]

Dr. Thames takes issue with the Jordi Lab procedure for removing tissue.[71] He states the Jordi protocol made no effort to remove ALL protein. We agree with this statement. We removed only enough material to allow for an accurate determination.[72] Dr Thames seemed to have missed the fact that a sample containing both protein and PP were identified as having both components. In my expert report, the IR bands observed at 1539, 1653 and 3300 cm^{-1} have been assigned to protein where as the ones at 1457, 1377, 1166, 998, 974 and 840 cm^{-1}have been

[68] Deposition of Howard C. Jordi, Ph. D., Pg 64
[69] Deposition of Howard C. Jordi, Ph. D., Pg 171
[70] Deposition of Howard C. Jordi, Ph. D., Pg 45-46
[71] Expert Report of Shelby F. Thames, Ph.D.; Pg 7
[72] Please see section 1 above for a full description of the scientific rationale for our sample preparation.

assigned to polypropylene. The spectrum shown in Fig. 3 clearly shows that these bands can be identified even when both materials are present. Thus my opinions are based on reliable results and are scientifically valid.

Dr. Thames argues that the carbonyl stretching bands are hardly discernible and intimates that they should be intense in the spectrum.[73] He also states that carbonyl bands should be between 1830 and 1650cm^{-1}. He therefore confirms our identification of the band at 1761 cm^{-1}as consistent with a carbonyl, but what Dr. Thames' ignores is that FTIR band intensity is a feature of not only the type of the band, but the concentration of the chemical species causing the signal observed.[74]This concept is well known and is established as Beer's law. Since oxidation does not have to occur at every monomer residue to have substantial degradation, the concentration of these functional groups can be low in a degraded material. Thus the peak intensity can also be low.

Dr. Thames inexplicably states no 1761 cm^{-1} shoulder in FTIR is visible in Sample 13413, particle 3.[75]However, Figure6 shows an overlay of the IR spectra of particles 2 and 3 for sample 13413. By comparing the intensities of the amide bonds with those for polypropylene, it is clear that amide bonds in particle 3 are much more intense as compared to particle 2. The reason why the 1761 cm^{-1}shoulder is largely obscured is due to the swamping out of the oxidation carbonyl by the protein carbonyl in this particular particle. Nevertheless, it is indisputable that 1455 and 1377 cm^{-1}bands are visible and are characteristic of PP, and furthermore all of the bands pertaining to the fingerprint region of polypropylene (1457, 1377, 1166, 998, 974 and 840 cm^{-1}) are present. The same explanation holds true for sample 13412 that the IR band at 1761 cm^{-1} was obscured by the highly intense protein bands.

[73] Expert Report of Shelby F. Thames, Ph.D.; Pg.7
[74]Skoog, D., Holler, F., Niemann, T., "Principles of instrumental Analysis," Saunders College Publishers, 1998, pg. 302, 381, 415.
[75] Expert Report of Shelby F. Thames, Ph.D.; Pg8

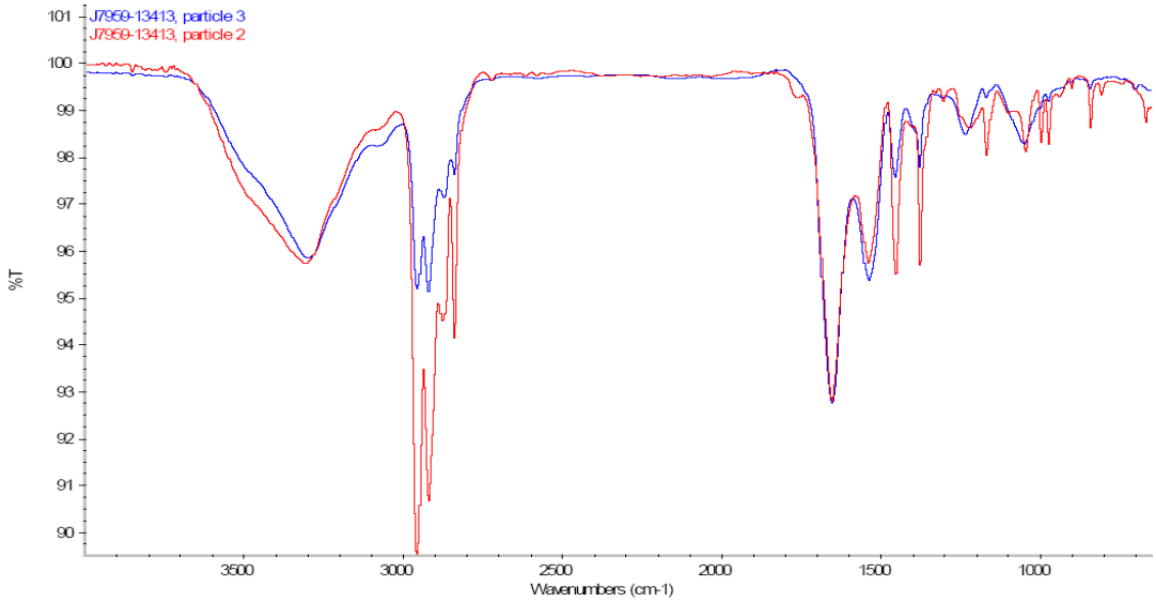

Figure 6. Overlay of FTIR spectra of particles collected from sample 13413

Dr. Thames' erroneously claims on two occasions that the FTIR spectrum showed no 1761cm^{-1} band observed in either of the two spectra of the Lewis samples.[76,77]Contrary to Dr. Thames' claim, the 1761 cm^{-1} band (indication of oxidation) is in fact obviously visible as shown in Fig. 3.[78]

It was argued by Dr. Thames that the less intense IR bands in the carbonyl region suggest that the oxidation did not occur.[79]What Dr. Thames' fails to appreciate, is that the band location, not the band intensity determines its identity, as described above, both the molar adsorptivity (signal strength per unit concentration) and concentration determine the peak magnitude.[80,81] There is no scientific basis or rationale for this comment by Dr. Thames.

Dr. Thames stated our band identification is wrong because it does not match the frequencies mentioned by Domagala[82], yetDr. Thames' stated on page 8 of his report that carbonyls can range from 1830-1650 cm^{-1}, thereby,acknowledging that the bandsI identifiedas carbonylsare in the correct range. The exact location of the carbonyl band is related to the type of

[76] Expert Report of Shelby F. Thames, Ph.D.; Pg9
[77] Expert Report of Shelby F. Thames, Ph.D.; Pg 10, paragraph 2
[78] Deposition of Howard C. Jordi, Ph. D., Pg 184
[79] Expert Report of Shelby F. Thames, Ph.D.; Pg9
[80]Skoog, D., Holler, F., Niemann, T., "Principles of instrumental Analysis," Saunders College Publishers, 1998, pg. 408-409
[81] Smith, A. Applied Infrared Spectroscopy, Fundamentals, Techniques, and Analytical Problem Solving, John Wiley & Sons, 1979, pg. 279-284.
[82] Expert Report of Shelby F. Thames, Ph.D.; Pg9

carbonyl group.[83]Moreover, the mechanism of oxidation in the Domagala study is vastly different compared to the mechanism of oxidation in the physiological environment of the explants. Therefore it is not necessary that the peak location be identical as the oxidation sources are different.

Dr Thames also claims that our peak identification at 1044 cm^{-1}frequency is incorrect.[84] As evidence for Dr Thames claim, he shows a reference spectrum for PP from the Aldrich polymer library. In this spectrum, he points out a weak band at 1049 cm^{-1}. Dr. Thames has failed to make a note of the increased peak intensity observed in our spectrum relative to pure polypropylene (Fig. 4).

Dr. Thamesalso argues that my opinion regarding Ethicon's 7 year dog study is inconsistent and that I admitted that the 7 year dog study did **not show** significant oxidation.[85]The 7 year dog study did not show significant oxidation but this does not mean that the surface was not oxidized. I found that the bulk technique of classical FTIR was not sensitive enough to examine the surface region. FTIR Microscopy which was used in our study is a more sensitive method as it can be focused onto only the cracked region. It appears that Dr. Thames has not distinguished between FTIR and FTIR Microscopy in our results.

In summary, all the issued raised by Dr. Thames as errors and inconsistencies have been invalidated by the above arguments regarding the FTIR data in my expert report. Dr. Thames confirmed the identity of cracked surface material as polypropylene as reported in our FTIR-microscopy by listing the following peaks as belonging to polypropylene(1457, 1377, 1166, 998, 974 and 840 cm^{-1}) (see **Table 1**).

	Comparison of the Bands in FTIR microscopy analyses (cm^{-1})					
Jordi Analysis	1455	1377	1168	998	973	841
Dr. Thames Analysis	1466	1380	1168	998	974	841

Table 1. Comparison of the fingerprint region in the Jordi analysis and Dr. Thames analysis in the FTIR spectra of Mrs. Lewis sample.

With regard to the peak observed at 1044 cm^{-1}, as explained earlier, Figure 4 in this report highlights the differences between the explant and control fibers, and clearly shows an increased intensity for the band at 1044 cm^{-1}. This was the basis of my statement regarding this peak. Neither Dr. Thames nor Dr. Ong provided microscopy images (only the spectrum was provided) which makes it impossible to determine the location from which they collected the spectrum.Dr. Thames presented incorrectly that the band intensity for carbonyl groups is always

[83] Smith, A. Applied Infrared Spectroscopy, Fundamentals, Techniques, and Analytical Problem Solving, John Wiley & Sons, 1979, pg. 279-284.
[84] Expert Report of Shelby F. Thames, Ph.D.; Pg 10
[85]Expert Report of Shelby F. Thames, Ph.D.; Pg 13

intense and failed to acknowledge that intensity is related to not only the type but also the concentration of the component under study. Peer reviewed papers, my 30 years of experience as a polymer scientist, and my data as a whole supports the conclusion that the cracked material is polypropylene and the FTIR data shows signs of polypropylene oxidation.

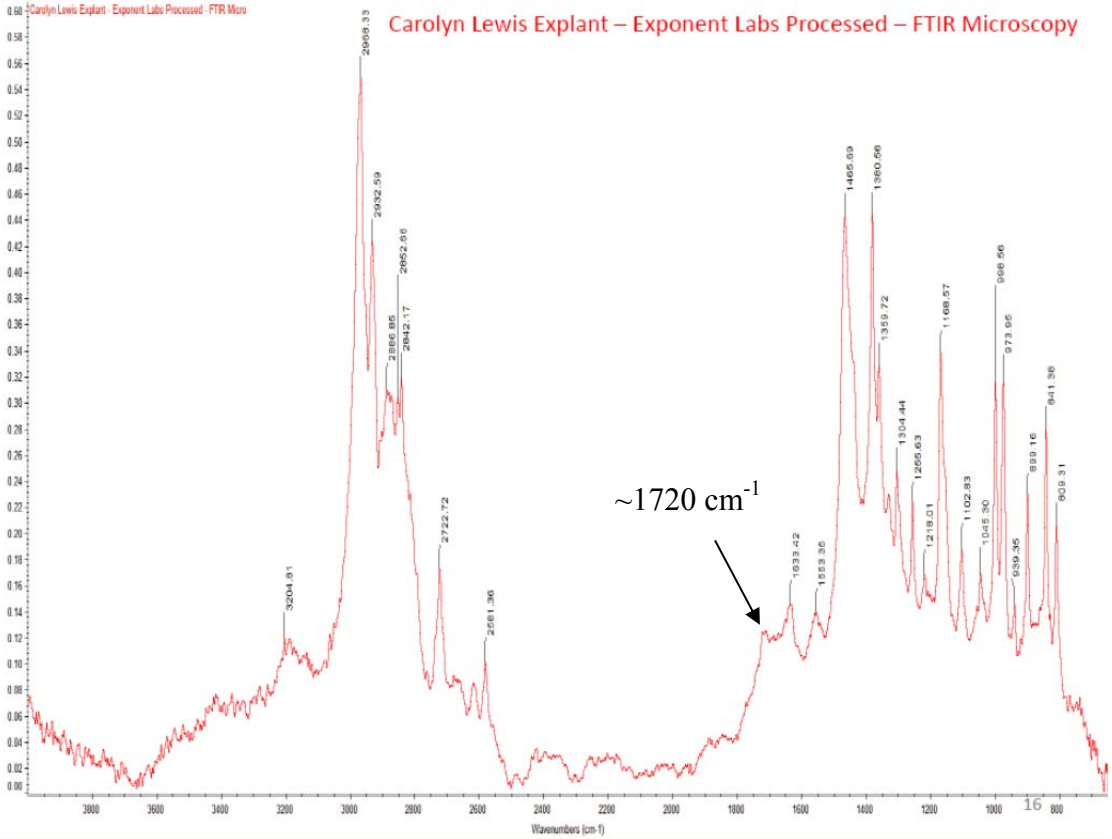

Figure 7. FTIR-microscopy spectrum of treated Lewis explants reproduced from Dr. Thames Report

VI. DSC

In reference to the DSC data in my expert report, Dr. Thames states that the number of noncracked samples tested was not sufficient to be considered reliable.[86] This is in spite of the fact that Dr. Thames analyzed only one explant sample and one exemplar, while we analyzed 23 (two uncracked) explants and 6 controls. Using Dr. Thames logic, his entire data set would be rejected as he only had one of each type.

Dr. Thames opines on page 6 of his expert report, that cracked/degraded polypropylene should show definable differences in the DSC data.[87] In Fig. 11 of his report, Dr. Thames showed that the thickness of the cracked layer is 3 um where as in Table 2, he shows that the

[86] Expert Report of Shelby F. Thames, Ph.D.; Pg18
[87] Expert Report of Shelby F. Thames, Ph.D.; Pg.6

diameter of the fibers is ~ 170um.[88] Thus the cracked surface represents a very tiny fraction of the overall thickness and thus surface cracking will tend not to show significant changes in DSC as it is a bulk technique. Therefore, it is difficult but not impossible to see changes in the bulk material.

Dr. Thames contends that the fact that some of the samples showed enthalpy values which were different than the expected value for a given level of cracking proves that the data is not meaningful.[89] This analysis is incorrect as it relies on the fallacy that only one factor is responsible for determining the extent of cracking. I do not argue that every sample which is cracked has to have a lower enthalpy, but rather that samples that have a lower enthalpy are more susceptible to cracking.[90] Dr. Thames argument is equivalent to stating that if a series of cars are observed to get into an accident and that the preponderance of those cars have brake problems, that every car that gets in an accident must have brake problems.

It was stated that there was insufficient sample to obtain TGA and DSC measurements,[91] but earlier in his report, Dr. Thames stated that Jordi Labs should have performed these tests;[92]however, Jordi Labs was also limited on sample quantity. Nevertheless, there was sufficient samples to obtain meaningful and reliable data which, when combined with my analysis of all the data obtained from the numerous tests conducted at Jordi Labs, to reach my opinion to a reasonable degree of scientific certainty, that Ethicon's polypropylene in the TVT meshes degrade as a result of oxidation and/or environmental stress cracking and degraded and cracked while inside Mrs. Lewis' body.

VII. SEM EDX

Dr. Thames stated that EDS determinations are unreliable for elements lighter than sodium.[93] As proof, he cites reference 38, Energy Dispersive Microanalysis, 1999. Since the time this book was written, significant progress has been made in the development of silicon drift detectors (SDD), which replaces the older Si(Li) detectors. The SDD is considered a significant advance precisely because they can be used to quantitate light elements. This was stated and well cited in my report.[94]

Dr. Thames states that there is no corroborating data provided to support the speculation that PP cracked.[95]However it was proved conclusively in our FTIR-microscopy data that the cracked material contains PP along with protein bands. A discussion of this primary conclusion of my report by Dr. Thames was conspicuously absent as already discussed in Section IV of this

[88] Expert Report of Shelby F. Thames, Ph.D.; Pg 26
[89] Expert Report of Shelby F. Thames, Ph.D.; Pg18
[90]Deposition of Howard C. Jordi, Ph. D., Pg 41
[91] Expert Report of Shelby F. Thames, Ph.D.; Pg23
[92] Expert Report of Shelby F. Thames, Ph.D.; Pg 13
[93] Expert Report of Shelby F. Thames, Ph.D.; Pg28
[94] Expert Report of Howard Jordi, Ph.D ; Pg 50
[95] Expert Report of Shelby F. Thames, Ph.D.; Pg15

report. Dr. Thames opinion that the cracked surface material is solely biofilm has no corroborating data and is unfounded as he cites no references and provides no data showing the analysis of the cracked material for identification purposes as shown earlier in this report.

Dr. Thames stated that "The Jordi testing confirmed that polypropylene did not oxidize."[96]As discussed previously, a peak at 1761 and a shoulder band at 1740 cm^{-1}were observed in the FTIR spectra of explanted samples. These peaksare consistent with oxidation of polypropylene. Moreover, the SEM-EDX data in my expert report shows conclusive evidence that both the cracked and uncracked regions of the explants samples showed increased levels of oxygen as compared to the control samples. These are clear indicators of oxidation, especially when considered along with the FTIR-microscopy data.

VIII. PYMS

Dr. Thames stated that scientific or analytical data was not provided to support diffusion of molecules like fatty acids and cholesterol into the polypropylene.[97]However, Figure 86 in my expert report shows a PYMS chromatogram overlay of Control *3422128* and Lewis sample explant.[98]PYMS stands for Pyrolysis Mass Spectrometry and uses high temperature to pyrolyze the polymers. Cholesterol (11.04 min) and cholesterol-like molecules (between 10.00 and 11.00 min) were detected in the PYMS of the Lewis sample. The data indicates that cholesterol may have diffused into the polypropylene chains. It can be stated with a reasonable degree of scientific certainty that all the cholesterol-like molecules may have resulted as pyrolysis products of cholesterol itself.

IX. LCMS

Dr. Thames also criticizes our LCMS data.[99]However, Dr. Thames completely ignores the fact that every instrument experiences drift over a period of days. This is why quantitative analysis is performed by running standards at the time the samples are analyzed. If instruments did not drift, then only one analysis of a standard would ever need to be performed. Accurate quantitation is obtained by comparing the peak area for the standard with that for the sample run at the same time. What Dr. Thames failed to observe was that the data he referenced regarding the peak area counts of Santonox-R in duplicate control samples was separated by almost 3.5 weeks. Any person skilled in the art would know that instrumental drift over this period of time would easily explain this difference. The purpose of running this control sample twice is exactly for this reason. The analysis was comparing the amount present in the extract of the control with the amount present in an explant sample similarly prepared. Since the samples were run on different dates, it was necessary to run the control twice precisely to account for this instrumental drift.

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[96] Expert Report of Shelby F. Thames, Ph.D.; Pg12
[97] Expert Report of Shelby F. Thames, Ph.D.; Pg14
[98] Expert Report of Howard Jordi, Ph.D ; Pg 82
[99] Expert Report of Shelby F. Thames, Ph.D.; Pg 16

As any good scientist would do, we recorded the data and observations in the expert report and lab notebooks, including data from the LCMS testing that showed formalin can extract Santonox R from polypropylene control samples. However, this data does not prove that Santonox-R did not leach before being exposed to formalin nor does it prove that sufficient antioxidants were present to prevent oxidation as the overwhelming evidence suggests otherwise. For example, it has been reported that in an oxygen rich aqueous environment, Santonox R is lost rapidly from polyolefins.[100]Having said that, according to Ethicon's internal documents,Santonox R (0.10-0.30%) is used as an antioxidant to promote stability during compounding and extrusion and thatDLTDP (0.40-0.60%)is used as an antioxidant to improve long-term storage of the resin and the fiber and to reduce the potential oxidative reaction with ultraviolet light.[101]Thus, neither Santonox R nor DLTDP were intended to prevent oxidation while implanted in the human body. It appears from Ethicon's documents, DLTDP which is at least twice as abundant as Santonox-R and promotes long term stability to polypropylene is the more important of the two. Furthermore, in Table 18 of my expert report, it is clearly noted that the DLTDP relative concentration is orders of magnitude lower in the explants as compared to the untreated or the formalin treated controls, making it susceptible to oxidation.[102]

Dr. Thames proposes that the phenolic antioxidant (Santonox R) is reacting with formaldehyde.[103] What Dr. Thames fails to point out is that this reaction requires acid or base catalysis.[104] The formalin solutions for three explant samples (J7959-13404, J7959-13411 and J8041-13474) were tested for pH analysis. The formalin solutions used for all the explants samples are neutral (pH 7.0).Additionally,high concentrations of formalin 36-50% aqueous solutions and heating (80-95 °C) are required in addition to acid and base catalysis for this reaction to occur. It is unfortunate that this historic and well established chemistry was not clearly explained in Dr. Thames report.

Dr. Thames states that DLTDP may be bound within the fiber and not extractable due to protein-formaldehyde polymer formed around the fiber.[105] The argument that the protein-formaldehyde polymer hinders the extraction of DLTDP is unfounded and Dr Thames provides no evidence or citations to support this claim and therefore it is not reliable.The analysis performed by Jordi Labs showed that the cracked surface material contained PP indicating that the surface is not completely encased in a protein coating which contradicts his argument. He further states that the extraction conditions used were mild and may not have been sufficient. He states this without support while ignoring the direct evidence contained in my expert report which clearly demonstrated that DLTDP was successfully dissolved from the control samples and was also sufficient to dissolve a DLTDP standard.

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[100]Marie Lundbäck "Long-term performance of polyolefins in different environments including chlorinated water: Antioxidant consumption and migration, and polymer degradation" PhD Thesis, 2005, KTH Fiber and Polymer Technology.

[101] ETH.MESH.02268619 – Prolene Resin Manufacturing Specifications

[102]Expert Report of Howard Jordi, Ph.D ; Pg200

[103] Expert Report of Shelby F. Thames, Ph.D.; Pg16

[104]George Odian, Principles of Polymerization, Third Edition, John Wiley & Sons, Inc., New York, NY, 1991, pages 125-132.

[105] Expert Report of Shelby F. Thames, Ph.D.; Pg17

Nevertheless, based on my knowledge, training, experience and skill, the body of scientific literature showing that polypropylene degrades *in vivo* and the analysis of all of our data, it is my opinion to a reasonable degree of scientific certainty that the polypropylene in Ethicon's TVT does degrade and in fact did degrade while implanted in Mrs. Lewis, regardless of the level of antioxidants present in the mesh while it was implanted in her body.

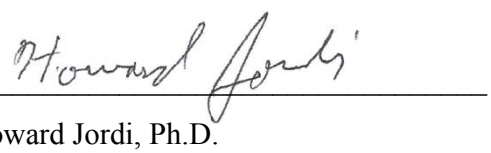
X. GPC

On page 12, paragraph 1 of Dr. Thames's report, he highlights that I concluded that in my report that no molecular weight change is equivalent to no degradation.[106]This is far from the truth. I redirect Dr. Thames' attention to the scientific opinions expressed on page 80 of my report where I state that "The control and explant samples do not show a significant difference in molecular weight. Because GPC-HT is a bulk technique (entire fiber is dissolved), changes in molecular weight may not be detectable given that the majority of the degradation is a surface phenomenon." Dr. Thames through his work has confirmed that the cracking is only a surface phenomenon and that the thickness of the cracked material is ~3um. This is approximately 2% of the total diameter of the fibers (~170um). Thus the contribution from the cracked portion to the molecular weight in relative terms would be insignificant compared to the contribution from the non-cracked portion of the explant fiber confirming our results that gross molecular weight degradation is not observed. As explained earlier in this report, the degradation by free radical attack is a surface phenomenon.The bulk of the polymer will not be attacked at least initially. Therefore, Dr. Thames contention that molecular weight changes are required to prove degradation by free radical attack is illogical and misleading. Additionally, the environmental stress cracking mechanism does not require changes in the molecular weight.

XI. Conclusion

The test methods used by me in forming my opinions are reliable. SEM, SEM-EDX, FTIR microscopy, DSC, PYMS, LCMS and GPC are generally accepted in the polymer scientific community and provide objective evidence that polypropylene used in TVT degrades. It is further my opinion to a reasonable degree of scientific certainty based on over 30 years of experience as a biochemical and polymer scientist, my review of peer-reviewed publications and the Jordi Lab testing, that Mrs. Lewis' TVT device degraded and cracked while implanted in her body as a result of oxidation or environmental stress cracking.

This 5th day of November, 2013



Howard Jordi, Ph.D.

[106] Expert Report of Shelby F. Thames, Ph.D.; Pg12

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO PLAINTIFFS: **Carolyn Lewis (2:12-cv-04301)**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

A copy of the foregoing was served via electronic delivery on the following counsel this 5th day of November, 2013:

William Gage
Butler, Snow, O'Mara, Stevens and Cannada, PLLC
P.O. Box 6010
Ridgeland, MS 39158

Christy Jones
Butler, Snow, O'Mara, Stevens and Cannada, PLLC
P.O. Box 6010
Ridgeland, MS 39158

By: */s/ Benjamin H. Anderson*
Benjamin H. Anderson
ben@andersonlawoffices.net
Ohio Bar No. 0067466
Member of Plaintiffs' Steering Committee

Anderson Law Offices
1360 W. 9th Street
Suite 215
Cleveland, Ohio 44113
(216) 513-8755